

REMARKS

The election of claims 26-30 without traverse is confirmed. New claims 39 to 44 have been added and are consistent with the restriction requirement.

I. Interview Summary

The courtesy of the Examiner during the interview of March 23, 2004, is appreciated. The Examiner's written interview summary is correct. During interview, applicants submitted a proposed set of amended claims which is substantively the same as the amended claims set forth above. However, the limitation "without intervention of a human operator" was added to claim 26 at the suggestion of the Examiner.

During the interview, applicants pointed out several distinctions between the claimed invention and the applied prior art including that the present invention: controls the blood flow through a blood circuit based on the pressure in the withdrawal and/or infusion blood lines; provides continuous and simultaneous blood withdrawal and infusion during a blood filtration session, and automatically increases blood flow after alleviation of an occlusion in the blood line.

II. Claimed Invention Is Patentable Over The Prior Art

The rejection of claims 26, 28-30 as being obvious over Prince (U.S. Patent No. 5,178,603) in view of Kitaevich et al. (U.S. Patent No. 5,211,849) is traversed.

Independent claim 26 has been amended to make clear that the control method is a continuous and simultaneous withdrawal, filtering and infusion of blood. In addition, the claimed control method reduces both filtrate flow and blood flow when an occlusion is

detected in the system. Further, claim 26 has been amended to make clear that the automatic increase in the blood flow through the circuit after an occlusion has been alleviated, occurs without intervention of a human operator regarding the pump operation. These features are not taught by the applied prior art.

Prince discloses a batch, single needle system for treating blood. As a batch system, Prince withdraws blood, separates plasma from the blood and infuses blood and saline into the patient in a serial manner. The operation of withdrawal and infusion of blood are done in Prince serially, at different time periods and as a batch system. Prince describes a batch plasmapheresis system that is not a continuous system and does not control the withdrawal, ultrafiltrate and infusion pressures simultaneously with a blood and ultrafiltrate pump. As a batch system, the Prince device does not contend with any changes in infusion pressure, withdrawal pressure and ultrafiltrate pressure simultaneously.

In contrast to Prince, the present invention withdraws and infuses blood continuously and simultaneously. The present invention is a parallel process blood circuit, which is in stark contrast to the batch system disclosed in Prince.

Kitaevich discloses a hemofiltration system having a weight controller that uses two weight scales. Kitaevich does not control based on withdrawal or infusion pressure. The controller described in Kitaevich pertains to a weight scale controller which adjusts the rate of infusate and ultrafiltrate in accordance with a weight trajectory. *See e.g.*, Kitaevich, col. 3, lines 5 to 24. The infusate and drain pumps are designed to operate

only when the blood pump is operating. Kitaevich (at col. 3, lines 25 to 30) describes adjusting a rate of blood pump flow but not ultrafiltrate pump flow to achieve a desired level of fluid removal in order to maintain a particular weight scale trajectory. The output of the controller in Kitaevich is blood flow rate and the input is the desired weight by the controller.

In contrast to Kitaevich, the present invention inputs to the controller the withdrawal and/or infusion pressure. Based on these inputs, the controller regulates the blood flow rate and the ultrafiltrate flow rate. Controlling blood flow and filtrate based on pressure inputs – as is done in the present invention – is dissimilar to and contrary to controlling blood flow based on the weight of a fluid collection bag, as is taught by Kitaevich.

The rejection of claim 27 for obviousness based on Prince in view of Kitaevich and Epstein et al (U.S. Patent No. 5,464,392) is traversed for the same reasons above.

Epstein shows the problem solved by the present invention was recognized but unsolved in the prior art. Epstein (col. 1, lns. 37- 50) states the problem is:

“The plural gravity flow controllers, however, are disadvantageous, among other things, due to the increased possibility of infection occasioned by multiple IV venipuncture; due to the flow inaccuracies occasioned, among other things, by patient movement induced tube occlusion or turning shape changes; due to the considerable labor and time required from a nurse or other health practitioner to manually control the plural gravity flow controllers in accordance with a prescribed course of therapy; due to clutter around the patient; and due to the possibility of out-of-control infusion occasioned by a failure of one or more of the gravity flow controllers.”

The solution to the problem of patient movement disclosed in Epstein (col. 2, lns. 1- 8) is:

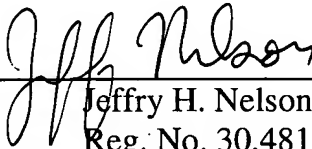
“The novel infusion system of the present invention contemplates means operable to controllably infuse pre-selected fluids from any one or more of plural fluid input ports either simultaneously or in time sequence through at least one patient output port and into the circulatory system of a patient in a predetermined time sequence.”

Other than minimizing the number of port connections to the patient, Epstein offers no solution for the prevention of an occlusion. Accordingly, Epstein teaches away from the claimed method.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone the undersigned. Prompt reconsideration and allowance of this application is requested.

Respectfully submitted,

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